RULEMAKING NOTICE FORM

Notice Number 2015-137	Rule Number	He-C 402 (various)
1. Agency Name & Address: NH Dept. of Health & Human Services Therapeutic Cannabis Program 129 Pleasant St. Concord, NH 03301	2. RSA Authority: 3. Federal Authority: 4. Type of Action: Adoption Amendment Repeal Readoption Readoption w/a	RSA 126-X:6, III X mendment X
5. Short Title: Therapeutic Cannabis Pro	ogram – Alternative Treatment	Centers

6. (a) Summary of what the rule says and of any proposed amendments:

He-C 402 sets forth the requirements necessary to establish, operate, and maintain an alternative treatment center (ATC) for the purposes of cultivating, processing, packaging, labeling, and dispensing therapeutic cannabis to qualifying patients and their designated caregivers.

The proposed rule makes the following changes to He-C 402:

- Implements a portion of SB 22 (Chapter 143 of the 2015 session), which clarifies the language regarding the prohibition of locating an ATC in a designated drug-free school zone.
- Implements a process for issuing a conditional registration certificate to an ATC for its cultivation location prior to its dispensing location being fully operational.
- Updates the supporting documentation required to be submitted by the ATC with its registration certificate application, initially and upon renewal, including the requirement to submit proof of registration with the NH Attorney General's Office that the ATC is a charitable trust under RSA 7:19.
- Establishes a date certain for the ATC's annual report to be submitted to the Department.
- Adds the requirement that the ATC submit the annual report required by RSA 7:28 to be filed with the Office of the NH Attorney General Charitable Trusts Unit to the Department as well.
- Updates He-C 402.15 regarding the laboratory testing of cannabis, as follows:
 - o Implements a portion of SB 22 (Chapter 143 of the 2015 session), which requires laboratories conducting testing of cannabis to be licensed under RSA 151.
 - Requires each batch of harvested cannabis and cannabis concentrate to be tested for microbiologicals, heavy metals, and toxins.
 - Requires quarterly testing of random batches of harvested cannabis and cannabis concentrate for prohibited pesticides and chemicals.
 - Establishes threshold limits of microbiologicals, heavy metals, toxins, and prohibited pesticides/chemicals.
 - o Requires certain test results to be sent directly to the department.
 - o Prohibits the sale and use of cannabis batches that fail to meet the established thresholds without Department authorization.
 - o Requires the ATC to develop and implement a policy for the collection and provision of cannabis samples which includes a statistically valid sampling methodology.
- Aligns the production of cannabis infused product restrictions for qualifying patients and designated caregivers with that being proposed in He-C 401.18 in a separate rulemaking.

6. (b) Brief description of the groups affected:

Groups affected by this rule include operators of the ATCs and their agents, qualifying patients and their designated caregivers who utilize the services of the ATCs to access therapeutic cannabis, and independent testing laboratories in NH which elect to perform testing of cannabis.

6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule	RSA Implemented
He-C 402.03(q)	RSA 126-X
He-C 402.05	RSA 126-X:7, IV(a); RSA 126-X:7, IX
He-C 402.06(c)	RSA 126-X:6, III(a)(1); RSA 126-X:7, V; RSA 126-X:7, IX
He-C 402.07(n)	RSA 126-X:6, III(a)(2)
He-C 402.08(m)	RSA 126-X:3
He-C 402.10 (q) intro & (r)	RSA 126-X:6, III(a)(2)
He-C 402.15	RSA 126-X:6, III(a)(5); RSA 126-X:7, IV(a)(9), IV(c)(5)
He-C 402.15(p)	RSA 126-X:2, XV
He-C 402.16 (a)	RSA 126-X:1, III, XV

	7.	Contact person	for co	opies and	questions	including	g requests to	accommodate	persons with	disabiliti
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Name: Michael Holt	Title:	Rules Coordinator
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Address: **Dept. of Health and Human Services** Phone #: **271-9234**

Administrative Rules Unit 129 Pleasant St. Fax#: 271-5590

Concord, NH 03301 E-mail: michael.holt@dhhs.state.nh.us

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

The proposed rules may be viewed and downloaded at: http://www.dhhs.nh.gov/oos/aru/comment.htm

8.	Deadline for	or submission of materials in writing or,	if practicable for the agency, in the electronic format
	specified:	September 11, 2015	
	⊠Fax	⊠E-mail	Other format (specify):

9. Public hearing scheduled for:

Date and Time: Thursday, September 3, 2015 at 2:00 PM

Place: DHHS Brown Bldg., Auditorium, 129 Pleasant St., Concord, NH

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant)

FIS # 15:148 , dated 08/06/15

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

When compared to existing rules, the proposed rules will have an indeterminable fiscal impact on independently owned businesses.

2. Cite the Federal mandate. Identify the impact of state funds:

No federal mandate, no impact on state funds.

3. Cost and benefits of the proposed rule(s):

A. To State general or State special funds:

None.

B. To State citizens and political subdivisions:

None.

C. To Independently owned businesses:

To the extent independently owned businesses produce cannabis and cannabis concentrate, the proposed rules will increase costs. The proposed rules require alternative treatment centers (ATCs) to (1) have an independent laboratory, located in New Hampshire, test cannabis prior to sale; and (2) develop and implement policies and procedures for such testing. The following table details the required testing and estimated costs:

Type of Testing	Estimated	Frequency
Performed	Cost	
Heavy Metals	\$100	Each Batch of Cannabis
Microbiologicals	\$130	Each Batch of Cannabis
Toxins	\$50	Each Batch of Cannabis
Pesticides	\$120	At Least Quarterly

To the extent ATCs conduct the abovementioned testing, independent laboratories will benefit from increased testing activities.

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules modify an existing program or responsibility, but do not mandate any fees, duties or expenditures on the political subdivisions of the state, and therefore do not violate Part I, Article 28-a of the N.H. Constitution.

CHAPTER He-C 400 THERAPEUTIC CANNABIS PROGRAM

PART He-C 402 ALTERNATIVE TREATMENT CENTERS

Amend He-C 402.03(q), effective 11/25/14 (Document #10731), cited and to read as follows:

He-C 402.03 Definitions.

(q) "Contaminant" means mold, fungus, bacterial diseases, rot, pests, non-organic pesticides, mildew, mycotoxins, heavy metals, and any chemical listed in He-C 402.34, Table 402.1.

Readopt with amendment He-C 402.05, effective 11/25/14 (Document # 10731), to read as follows:

He-C 402.05 Registration of ATCs.

- (a) Only an ATC that is currently registered by the department and has been issued a registration certificate may dispense cannabis, CIP, or paraphernalia to qualified patients and designated caregivers who have been issued a registry identification card from the department; however, an entity that has been issued a conditional registration certificate in accordance with (1) below may cultivate cannabis and produce CIP in anticipation that the entity will become fully operational and ready to begin dispensing cannabis as a registered ATC.
- (b) Each ATC selected as part of the RFA process shall provide to the department the fee of \$20,000 in accordance with He-C 402.04(b)(1) or \$10,000 in accordance with He-C 402.04(c)(1) within 10 days of the department's notice that the entity has been selected. Failure to provide the fee within the required timeframe shall result in forfeiture of the selection and shall prevent the entity from submitting an application in (c) below.
- (c) Each ATC selected as part of the RFA process shall submit the following to the department within 90 days of the department's notice that the entity has been selected:
 - (1) A completed application:
 - a. Signed by the applicant or 2 of the corporate officers affirming the following:
 - "I affirm that I have read and understand the requirements of RSA 126-X and the rules adopted thereunder and that the premises are in compliance with that statute and rule. I understand that providing false or misleading information shall be grounds for denial, suspension, or revocation of the registration and the imposition of a fine."; and
 - b. Containing the following information:
 - 1. The name of the ATC:
 - 2. The physical address of the ATC and, if applicable, the physical address of a second location for cultivation and processing operated by the ATC;
 - 3. The mailing address of the ATC if different from the physical address;
 - 4. The telephone number of the ATC;

- 5. The name of the ATC's administrator; and
- 6. The email address for the ATC's administrator, and for the ATC if different;
- (2) A "Certificate of Good Standing" issued by the NH secretary of state authorizing the ATC to do business as a not-for-profit corporation in the state of New Hampshire;
- (3) Proof of registration with the NH attorney General's office as a charitable trust under RSA 7:19 et seq for the benefit of qualifying patients;
- (3)(4) A copy of the ATC's articles of agreement;
- (4)(5) A copy of the ATC's bylaws;
- (5)(6) A statement detailing any instances in which a prospective board member, corporate officer, or executive employee who previously ran a business or managed or sat on the board of directors of a corporation was convicted, fined, censured, or had a registration, certification, or license suspended or revoked in any administrative or judicial proceeding, or any instances in which the business or corporation itself was subject to such an action, if this information was not included in the RFA application;
- (6)(7) A floor plan of the prospective ATC, to include a complete description and layout of the indoor, enclosed, locked facility, in which all limited access areas are clearly indicated in the diagram of the registered premises, reflecting walls, partitions, counters, and all areas of entry and exit. Said diagram shall also show all propagation, vegetation, flowering, processing, production, storage, disposal, and retail sales areas;
- (7)(8) The application fee of \$30,000 in accordance with He-C 402.04(b)(2) or \$15,000 in accordance with He-C 402.04(c)(2);
- (8)(9) An organization chart and Rresumes identifying the qualifications of:
 - a. The executive employees of the ATC; and
 - b. The ATC board members and corporate officers;
- (9)(10) The name, address, and date of birth of each executive employee and corporate officer of the ATC;
- (10)(11) The name, address, and date of birth of each member of the board of directors of the ATC, which shall:
 - a. Include at least one physician, advance practice registered nurse, or pharmacist licensed to practice in New Hampshire, except that such medical professional shall not maintain an ownership interest in the ATC;
 - b. Include at least one patient qualified to register as a qualifying patient; and
 - c. Consist of a majority of New Hampshire residents;
- (11)(12) Written local approvals as follows:

- a. For an existing building, the following written local approvals shall be obtained no more than 90 days prior to submission of the application, from the following local officials or if there is no such official(s), from the board of selectmen or mayor:
 - 1. The health officer verifying that the applicant complies with all applicable local health requirements, drinking water and wastewater requirements;
 - 2. The building official verifying that the applicant complies with all applicable state building codes and local building ordinances;
 - 3. The zoning officer official verifying that the applicant complies with all applicable local zoning ordinances; and
 - 4. The fire chief verifying that the applicant complies with the state fire code, including, but not limited to, the applicable chapter of NFPA 101 as adopted by the department of safety, and local fire ordinances applicable for an agricultural processing and retail sales facility; and or
- b. For a building under construction or undergoing renovation:
 - 1. The local approvals of the construction or renovation plans; and
 - 2. The final local the written approvals required by a. above shall be submitted upon completion of the construction or renovation project;
- (12)(13) The results of a federal and NH state criminal records check for every corporate officer, board member, and executive employee pursuant to RSA 126-X:8, IV(a), and RSA 126-X:4, II-a;
- (13)(14) If the ATC uses a private water supply, documentation that the water supply has been tested in accordance with and meets the requirements of RSA 485 and Env-Dw 700;
- (14)(15) The distance, in feet, from the property line or extended drug free zone of any preexisting designated drug-free school zone private or public preschool, kindergarten elementary or secondary school located within 1320 feet of the registered premises;
- (15)(16) A list of all persons or entities not included in the RFA and having direct or indirect authority over the management or policies of the ATC, including the members of the not-forprofit corporation, and a list of all persons or entities contributing 5% \$5000 or more of the initial capital to operate an ATC, including capital that is in the form of land or buildings. Identify any conditions on such funds or property; and
- (16)(17) Documentation of liability insurance coverage in the amount of 2 million dollars.
- (d) The applicant shall mail or hand-deliver the documents in (c) above to:

Department of Health and Human Services Health Facilities Administration Therapeutic Cannabis Program 129 Pleasant Street Concord, NH 03301

- (e) An application for an initial registration shall be complete when the department determines that all items required by (c) above have been received.
- (f) If an application does not contain all of the items required by (c) above, the department shall notify the applicant in writing of the items required before the application can be processed.
- (g) Any fees submitted to the department in the form of a check or money order and returned to the state for any reason, shall be processed in accordance with RSA 6:11-a.
 - (h) Registration fees shall not be transferable to any other application(s).
- (i) The department shall deny a registration certificate request in accordance with RSA 126-X:8,V, after reviewing the information in (c)(12) above if it determines that a corporate officer, a board member, or executive employee has been convicted of a felony in this or any other state.
- (j) Following an inspection, a notice of registration approval shall be issued if the department determines that an applicant requesting an initial registration is in full compliance with RSA 126-X and He-C
- (k) Upon receipt of the notice of registration approval in (j) above, the entity shall submit the final \$30,000 of the initial registration fee in accordance with He-C 402.04(b)(3) or the final \$15,000 of the initial registration fee in accordance with He-C 402.04(c)(3).
- (1) Notwithstanding (j) above, if an entity intends to have a cultivation location separate from its dispensing location, and if it completes construction of the cultivation location before it completes construction of the dispensing location or is otherwise not ready to begin dispensing cannabis, the department shall issue a conditional registration certificate authorizing the entity to begin cultivation and CIP production prior to the time it is ready to begin dispensing, provided that:
 - (1) The entity has submitted an application for a registration certificate;
 - (2) The entity has paid all non-refundable fees required under He-C 402.04(b)(1)-(3) or 402.04(c)(1)-(3);
 - (3) The entity has received local approvals for the cultivation location required under He-C 402.05(c)(11); and
 - (4) The cultivation location has been inspected by the department and found to be in full compliance with RSA 126-X and these rules.
- (m) If a conditional registration certificate is issued under (l) above, the entity shall not open its dispensing location and shall not dispense or sell any cannabis until such time as the department has inspected the dispensing location, found it to be in full compliance with RSA 126-X and these rules, and informed the entity in writing that it may open its ATC to qualifying patients and designated caregivers and begin dispensing cannabis.
- (n) In the event that a conditional registration certificate is issued under (l) above and, for whatever reason, the entity does not subsequently open its dispensing location pursuant to RSA 126-X:7, VIII, any cannabis cultivated shall be considered waste and shall be destroyed in accordance with He-C 402.22 under the supervision of the department.

(1)(o) A registration shall be effective on the date of issue and for a period of one year from the last day of the month in which it is issued. In the event a conditional registration certificate is issued in accordance with (1) above, the registration shall expire one year from the last day of the month that the conditional registration was issued.

Amend He-C 402.06(c), effective 11/25/14 (Document #10731), cited and to read as follows:

He-C 402.06 Renewal Requirements for ATCs.

- (c) The ATC shall submit with the renewal application:
 - (1) The materials required by:
 - a. He-C 402.05(c)(1);
 - b. He-C 402.05(c)(3);
 - c. He-C 402.05(c)(4) and (5), if either has changed;
 - d. He-C 402.05(c)(6), for new personnel or new instances involving existing personnel;
 - e. He-C 402.05(c)(7), if changed;
 - f. He-C 402.05(c)(9), for new personnel; and
 - g. He-C 402.05(c)(10) and (11), for new personnel or if the name or address of any existing personnel has changed;
 - (2) The renewal application fee of \$40,000 pursuant to He-C 402.04(d)(1), or \$20,000 pursuant to He-C 402.04(e)(1);
 - (3) If the ATC uses a private water supply, documentation that the water supply has been tested in accordance with and meets the requirements of RSA 485 and Env-Dw 700;
 - (4) The current registration number and expiration date;
 - (5) A request for renewal of any existing non-permanent waiver previously granted by the department, in accordance with He-C 402.26, if applicable; and
 - (6) A copy of any existing, non-permanent variances and any new variances applied for or granted by the state fire marshal, in accordance with Saf-C 6005.03 and Saf-C 6005.04.

Amend He-C 402.07, effective 11/25/14 (Document #10731), by inserting new paragraph (n) and renumbering subsequent paragraphs, so that paragraph (n) is cited and reads as follows:

He-C 402.07 Requirements for Organizational or Service Changes.

(n) An inspection by the department shall be conducted in accordance with He-C 402.28 prior to operation for all renovations and new construction at the ATC.

Amend He-C 402.08(m), effective 11/25/14 (Document #10731), cited and to read as follows:

He-C 402.08 Prohibitions.

(m) No ATC shall be located in a zoned-residential district or within 1000 feet of the pre-existing drug-free school zones of a pre existing public or private preschool, kindergarten, elementary, or secondary school.

Amend He-C 402.10, effective 11/25/14 (Document #10731), by amending paragraph (q) intro, and adding new paragraph (r), so that paragraph (q) intro and paragraph (r) are cited and read as follows:

He-C 402.10 Operational Requirements.

- (q) The ATC shall submit an annual report to the department, not later than October 1, containing the following information:
- (r) Within 10 days of filing the annual report required by RSA 7:28 with the office of the New Hampshire attorney general charitable trusts unit, the ATC shall file the report with the department.

Readopt with amendment He-C 402.15, effective 11/25/14 (Document #10731), to read as follows:

He-C 402.15 Testing.

- (a) Each batch of cannabis harvested and each batch of cannabis concentrate produced shall be tested in accordance with this section.
- (b) Each batch of cannabis harvested and each batch of cannabis concentrate produced shall be tested for its cannabinoid profile, to include at a minimum, THC, THCV, CBC, CBD, CBDV, CBN, and CBG, The testing required by this section shall be performed by an independent laboratory located in New Hampshire and licensed under RSA 151 that is:
 - (1) Accredited to International Organization for Standardization (ISO) 17025 by a third party accrediting body such as American Association for Laboratory Accreditation (A2LA) or ANSI-ASQ National accreditation Board (ACLASS); or
 - (2) Certified under the Clinical Laboratory Improvement Act (CLIA).
- (c) Each batch of cannabis harvested and each batch of cannabis concentrate produced shall be tested for:
 - (1) The cannabinoid profile; and
 - (2) Contaminants described in (d) below.
 - (d) The testing required by (c)(2) above shall meet the following standards:
 - (1) For purposes of testing for microbiologicals and mycotoxins, a cannabis sample shall be deemed to have passed if it does not exceed the limits set forth in the table below:

Cannabis	Viable	Yeast &	Viable	Bile-tolerant	E. Coli	Mycotoxins*

Material	Aerobic Bacteria (CFU/g)	Mold (CFU/g)	Coliforms (CFU/g)	Gram Negative Bacteria (CFU/g)	(pathogenic strains) & Salmonella spp.	
Harvested Cannabis	<u>10⁵</u>	<u>10</u> ⁴	<u>10³</u>	103	None detected in 1 gram	<20 μg /kg of material
Cannabis Concentrate	<u>10</u> ⁴	<u>10³</u>	<u>10²</u>	<u>10²</u>	None detected in 1 gram	<20 μg /kg of material

CFU: colony forming unit

*Mycotoxins include alfatoxin B1, alfatoxin B2, alfatoxin O1, alfatoxin O2, and ochratoxin A

(2) For purposes of testing for heavy metals, a cannabis sample shall be deemed to have passed if it does not exceed the limits set forth in the table below:

Heavy Metal	<u>Limit</u>
Arsenic	4,206 ppb
<u>Cadmium</u>	2,704 ppb
Lead	8,712 ppb
Mercury	8,712 ppb

ppb: parts per billion

- (e) The department shall require testing for the presence of prohibited pesticides and prohibited chemicals listed in He-C 402.34, Table 402.1, as follows:
 - (1) Testing shall be conducted for cannabis harvested and cannabis concentrate produced at each cultivation location;
 - (2) Testing shall be conducted at least quarterly;
 - (3) The department shall directly notify the laboratory when such testing shall be conducted; and
 - (4) Testing shall be conducted on samples provided to the laboratory for testing required by (c) above;
 - (5) Testing results shall be sent from the laboratory to both the department and the ATC; and
 - (6) A cannabis sample shall be deemed to have passed if no individual prohibited pesticide or chemical for which the laboratory tested is detected above 10 parts per billion.
- (f) Each batch of solvent-based cannabis concentrate shall be tested for residual solvents, which, except for ethanol and isopropanol, shall not exceed 500 parts per million.
- (g) The ATC shall segregate and withhold from use each batch of harvested cannabis and cannabis concentrate until the laboratory has completed its testing and presented its results in writing to the ATC.
- (h) In addition to test results described in (e)(5) above, the laboratory shall send to the department copies of each test result that fails to meet the standards in (d) and (f).

- (i) Any cannabis batch whose test sample fails to pass the standards in (d)-(f) above shall be permitted for use or sale only under conditions specified in writing by the department, such as requiring disclaimers or notifications being made to qualifying patients and designated caregivers at the point of sale, or the cannabis batch shall be destroyed and discarded as waste in accordance with He-P 402.22.
- (e)(j) An ATC shall be required to have CIP re-tested for its cannabinoid profile when the department determines that there is reason to believe that the cannabinoid profile on the label of the CIP does not accurately reflect the actual CIP cannabinoid profile. Copies of the testing results shall be sent to the department from the laboratory.
- (d)(k) Where testing under (e)(j) above indicates that the cannabinoid profile on the label does not accurately reflect its contents, the department shall be authorized to place conditions on the sale of such product, such as requiring disclaimers or notifications, or to seize, order recalls, or order destruction of such cannabis or CIP.
- (e) Each batch of solvent-based cannabis concentrate shall be tested for residual solvents, which, except for ethanol and isopropanol, shall not exceed 500 parts per million per gram.
 - (f)(1) The ATC shall maintain the results of all testing for no less than 4 years.
- (g)(m) The department shall require additional testing, copies of results for which shall be sent to the department, order recalls, or order destruction of cannabis or CIP:
 - (1) In the event it has evidence of tampering or product contamination;
 - (2) In order to determine the presence or absence of contaminants; or
 - (3) In order to verify the accuracy of labeling.
- (h)(n) Prior to transferring a cannabis sample to a laboratory for testing, the ATC shall require tThe testing laboratory to-shall supply documentation to the ATC of the test sample size requirements, for all analytes tested, to determine a minimum yet adequate amount of cannabis required by the laboratory to perform the testing required by this section (b), (c), or (e) above.
- (o) The ATC shall develop and implement a policy describing the procedures used to collect and provide samples for testing, which meets the following requirements:
 - (1) The ATC shall utilize a statistically valid sampling methodology to ensure that each sample is a random, homogenized sample; and
 - (2) The ATC shall document each sample collection, to include batch information, collecting agent information, and chain of custody information.
- (i)(p) Laboratories and laboratory employees shall be permitted to possess cannabis on the premises of the laboratory for the purpose of testing in accordance with this section.
 - (i)(r) ATCs shall be responsible for all costs associated with the testing of cannabis samples.
- (k)(s) No ATC agent shall have any financial or other interest in a laboratory providing testing services in accordance with this section.

(1)(t) No individual employee of a laboratory providing testing services for ATCs may receive direct financial compensation from any ATC.

(m)(u) All storage of cannabis at a laboratory providing cannabis-testing services shall comply with He-C 402.17.

Amend He-C 402.16(a), effective 11/25/14 (Document #10731), cited and to read as follows:

He-C 402.16 Production of Cannabis-Infused Products.

(a) Except for registered qualifying patients or designated caregivers, subject to the limitations in He-C 402.18, only a registered ATC shall be permitted to produce CIP.

APPENDIX

RULE	STATUTE
He-C 402.03(q)	RSA 126-X
He-C 402.05	RSA 126-X:7, IV(a); RSA 126-X:7, IX
He-C 402.06(c)	RSA 126-X:6, III(a)(1); RSA 126-X:7, V; RSA 126-X:7, IX
He-C 402.07(n)	RSA 126-X:6, III(a)(2)
He-C 402.08(m)	RSA 126-X:3
He-C 402.10 (q) intro & (r)	RSA 126-X:6, III(a)(2)
He-C 402.15	RSA 126-X:6, III(a)(5); RSA 126-X:7, IV(a)(9), IV(c)(5)
He-C 402.15(p)	RSA 126-X:2, XV
He-C 402.16 (a)	RSA 126-X:1, III, XV